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EXAMINER	
KUMAR, VINOD	
ART UNIT	**PAPER NUMBER**
1638	

NOTIFICATION DATE	DELIVERY MODE
11/16/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/553,124	ENDO ET AL.	
	Examiner	Art Unit	
	Vinod Kumar	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *12-18,28-41 and 43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,19-27,42,45,46,48 and 49* is/are rejected.

7)☒ Claim(s) *44, 47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 October 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of objections and rejections

1. Office acknowledges the receipt of Applicant's response filed on August 20, 2007. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 1-43, and newly added claims 44-49 are pending. Claims 1-11, 19-27, 42 and newly added claims 44-49 are examined on merits in the instant Office action. The objection to the specification is withdrawn light of amendment to the specification filed in the paper of August 20, 2007. All previous claim rejections not set forth below have been withdrawn in view of claim amendments filed in the paper of August 20, 2007. This action is made FINAL.

Election/Restriction

2. Claims 12-18, 28-41 and 43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 20, 2007. The restriction was made FINAL in the Office action mailed on April 20, 2007.

This application contains claims 12-18, 28-41 and 43 drawn to inventions nonelected with traverse in the reply filed on February 20, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

3. Drawings remain objected to because they fail to comply with 37CFR 1.83.

Figure 17 remains objected because it fails to comply with 37 CFR 1.84(g) for the reasons of record stated in the Office action mailed on August 20, 2007. Applicants traverse the objections to Figure 17 in the paper filed on August 20, 2007.

Applicants argue that the solid line in Figure 17 is not a frame but rather is an illustration of the boundary of the membrane to which the content of electrophoresis gel was transferred. Applicants further argue that the Figure 17 shows the results of a Southern hybridization assay where the probe is the kanamycin-tolerant (NPT) gene region of pBI121, and thus following hybridization and detection, any molecular size marker present in the original electrophoresis gel would not be detected (response, page 19, line 14 through the end of 1st paragraph of page 20).

Applicant's arguments were fully considered but were not found to be persuasive. It is maintained that Figure 17 is framed because all the existing labels (see numbers 1-5) are within the box. Applicant is also reminded that it is absolutely important to know the molecular size of hybridizing band so that one skilled in the art can distinguish what

is being hybridized within the restriction enzyme digested plant genome. This is a well-established protocol in the art of electrophoresis basis DNA/RNA hybridization experimentation, such as a Southern blot.

Regarding molecular size determination on a Southern blot, Applicants are also reminded that it is a routine practice to have hybridization solution carry probes specific to marker DNA and target DNA. Alternatively, hybridized band of a Southern blot are aligned with the ethidium bromide stained DNA gel (used for Southern blot) picture, which have DNA markers to determine the molecular size of hybridizing bands. These are routine and well established protocols.

In view of above, the objection is maintained and appropriate corrections are required.

Claim Objections

4. Newly added claims 44-49 are objected to because of the following informalities:

Claims 44-49 recite "(a)", "(b)", "(c)", "(d)", "(e)", and "(f)", respectively, which is unnecessary because it does not read properly. It is suggested to delete said recitations.

Claim 45 is objected for lacking the punctuation mark "." at the end of claim.

Appropriate corrections are required.

Claim Rejections - 35 USC § 112

5. Claims 1-11, 19-27, and 42 remain, and newly added claims 45-46, and 48-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleotide sequence encoding the protein of SEQ ID NO: 2, a salt tolerant transgenic plant and a method of producing plant comprising said nucleotide sequence, does not reasonably provide enablement for (a) an isolated polynucleotide encoding a protein having at least 95% sequence identity to SEQ ID NO: 2 and exhibiting the activity of imparting salt tolerance in plants or having UDP-glucose 4-epimerase activity, and (b) an isolated polynucleotide consisting a nucleotide sequence having at least 95% sequence identity to SEQ ID NO: 1 and encoding a protein exhibiting the activity of imparting salt tolerance in plants or having UDP-glucose 4-epimerase activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for the reasons of record stated in Office action mailed on April 20, 2007. Applicant traverses the rejection in the paper filed on August 20, 2008.

Applicants argue that as in *Ex parte Bandman*, the present specification provides the amino acid sequence (SEQ ID NO: 2) and the polynucleotide SEQ ID NO: 1 encoding SEQ ID NO: 2. Applicants further argue that the instant claims specify the activity required for all proteins encoded by the claimed polynucleotide that fall within the scope of instantly claimed invention (response, page 17, lines 4-10).

Applicant's arguments were fully considered but were not found to be persuasive. Applicant's attention is drawn to page 6 of USPTO's Board of Patent Appeals and Interferences decision on *Ex parte Bandman*, wherein it is noted that Board's decision was based on "sequences having 95% sequence identity to SEQ ID NO: 1, but also have a naturally occurring amino acid sequence". However, the instant claims (sequences 95% identity to SEQ ID NOs: 1 or 2) do not require naturally occurring amino acid sequence. The instant claims with 95% sequence identity to SEQ ID NO: 1 or 2 are significantly broader in scope compared to *Ex parte Bandman* claims. It may also be noted that the opinion rendered by the USPTO Board of Patent Appeals and Interferences was **not** the binding precedent of the Board (see page 1 of *Ex parte Bandman*).

It is thus, maintained that claim 1, and newly added claims 45-46 are directed to nucleotide sequences encoding proteins having at least 95% sequence identity to SEQ ID NO: 2, which would encompass unspecified amino acid changes within the amino acid sequence of SEQ ID NO: 2. Nucleotide sequences encoding proteins with 95% identity to the 364 amino acid long SEQ ID NO: 2 would encode proteins with 18% amino acid substitutions relative to SEQ ID NO: 2.

Likewise, claim 2, and newly added claims 48-49 are directed to a nucleotide sequence having at least 95% sequence identity to SEQ ID NO: 1, and which would encompass encoded proteins having unspecified amino acid changes compared to SEQ ID NO: 2. A 95% sequence identity to instant SEQ ID NO: 1 of 1154 nucleotides

in length, and comprising 1082 nucleotides of coding sequence would encode proteins having less than 80% sequence identity to instant SEQ ID NO: 2.

It is, therefore, maintained that while the specification provides guidance on using a nucleotide sequence encoding SEQ ID NO: 2 in a method of producing transgenic plants with increased stress tolerance. However, specification does not provide guidance on using sequences encoding proteins having less than 100% sequence identity to SEQ ID NO: 2, in a method of producing salt tolerant transgenic plants or transgenic plants exhibiting increased UDP-glucose 4-epimerase activity.

As discussed in detail in previous Office action that making amino acid changes in SEQ ID NO: 2 protein is unpredictable. While it is known that many amino acid substitutions, additions or deletions are generally possible in any given protein the positions within the protein's sequence where such amino acid changes can be made with a reasonable expectation of success (without altering protein function) are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These regions can tolerate only relatively conservative substitutions or no substitutions. See Keskin et al., Thornton et al. and Guo et al. as discussed in previous Office action. It is thus, maintained that neither the state of art nor Applicants provide guidance as to how inoperable embodiments can be readily eliminated other than random trial and error. The additions, deletions or substitutions of one or more amino

acid residues would also encompass changes in the functionally important domain(s) of the encoded protein. In the absence of guidance, it would have been highly unpredictable at the time the claimed invention was made that a sequence having at least 95% sequence identity to SEQ ID NO: 1 or SEQ ID NO: 2 could have been used in a method of producing a stress tolerant transgenic plant.

In the absence of adequate guidance, it is maintained that undue experimentation would have been required by a skilled artisan at the time claimed invention was made to determine how to use a sequence having at least 95% sequence identity to SEQ ID NO: 1 or SEQ ID NO: 2, in a method of producing salt tolerant transgenic plant exhibiting increased UDP-glucose 4-epimerase activity. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

6. Claims 1-11, 19-27, and 42 remain, and newly added claims 45-46, and 48-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record stated in Office action mailed on April 20, 2007. Applicants traverse the rejection in the paper filed on August 20, 2008.

Applicants argue that Example 14 of the synopsis of application on written description, USPTO has concluded that a claim is adequately described within the meaning of 35 USC § 112, first paragraph if the sequence has at least 95% sequence identity to the reference sequence (response, page 17, line 11 through the end of 1st paragraph of page 18).

Applicant's arguments were fully considered but were not found to be persuasive. Applicants are reminded that instant claims directed to 95% sequence identity to SEQ ID NOs: 1 or 2 is not analogous to the claim in Example 14 of USPTO guidelines on written description. The claim of Example 14 of guidelines recites 95% sequence identity to SEQ ID NO: 3 which encompasses a significantly small genus of sequences, as compared to instant claims 1, and 45-46 which recite 95% sequence identity to SEQ ID NO: 2 or claims 2, and 47-48 which recite 95% sequence identity to SEQ ID NO: 1. The instant claims encompass significantly a large genus of sequences compared to the claim in Example 14 of guidelines. For example, instant claim 1, and newly added claims 45-46 directed to a nucleotide sequence having at least 95% sequence identity to SEQ ID NO: 2 would encompass unspecified amino acid changes within the amino acid sequence of SEQ ID NO: 2. Nucleotide sequences encoding proteins with 95% identity to the 364 amino acid long SEQ ID NO: 2 would encode proteins with 18% amino acid substitutions relative to SEQ ID NO: 2. Likewise, claim 2, and newly added claims 48-49 directed to a nucleotide sequence having at least 95% sequence identity to SEQ ID NO: 1 would encompass unspecified amino acid changes within the amino acid sequence of the encoded protein of SEQ ID NO: 2. A 95% sequence identity to

instant SEQ ID NO: 1 of 1154 nucleotides in length, and comprising 1082 nucleotides of coding sequence would encode proteins having less than 80% sequence identity to instant SEQ ID NO: 2. It is, therefore, maintained that the instant case specification fails to correlate a large number of undisclosed structures of the Applicant's broadly claimed genus to the function of increased salt tolerance and/or UDP glucose-4-epimerase activity.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

Also see in re Curtis (69 USPQ2d 1274 (Fed. Cir.2004), where the court held that there was sufficient evidence to indicate that one of ordinary skill in the art could not predict the operability of other species other that the single one disclosed in the specification. The court held that a disclosure naming a single species can support a claim to a genus that includes that species if a person of ordinary skill in the art, reading the initial disclosure, would "instantly recall" additional species of the genus already "stored" in the minds, but if other members of the genus would not "naturally occur" to a

person of ordinary skill upon reading the disclosure, then unpredictability in performance of species other than specifically enumerated defeats claims to the genus.

For at least these reasons and the reasons of record stated in the previous Office Action, the requirement for written description has not been met.

Allowable Subject Matter

7. Newly added claims 44 and 47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusions

8. Claims 1-11, 19-27, 42 and newly added claims 45-46, and 48-49 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is set to expire within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and

any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER